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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,937	10/02/2001	Raymond R. Hannigan	VAC .482	8701

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ATTN: LEGAL-MANUFACTURING
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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,937

Applicant(s)

HANNIGAN ET AL.

Examiner

Kim M. Lewis

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 and 25-27 is/are allowed.
- 6) ☒ Claim(s) 7-12, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 20-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Summary

1. The amendment filed on 10/14/04 has been received and made of record. As requested claims 11 and 12 have been amended and claim 13 has been canceled.
2. Claims 7-12 and 18-27 are pending in the instant application.
3. The indicated allowability of claims 18 and 19 are withdrawn in view U.S. Patent No. 6,398,767. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,398,767 ("Fleischmann").

As regards claim 7, Fleischmann discloses a process and device for application of active substances to a wound surface area, which anticipates applicant's presently claimed invention. More specifically, Fleischmann discloses a method for promoting wound healing comprising the steps of: packing a wound site (10) at a region on a mammal with a foam pad (12) (Fig. 1), said foam pad being in fluid communication with

Art Unit: 3743

a vacuum source (col. 4, line 42); sealing the region, including said foam pad, with a wound drape (14) (col. 4, lines 15-43); and communicating a vacuum from said vacuum source through said foam pad to the region (abstract, and inherently effecting a change in the mammal's inflammatory response at said region while said vacuum is applied thereto.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 8-10, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischmann in view of U.S. Patent No. 4,382,441 ("Svedman").

As regards claim 8, Fleischmann discloses circulating a fluid about said region, but fails to teach controlling the temperature of the fluid to obtain the change.

Art Unit: 3743

Svedman, however, discloses a device for treating tissues which device comprises a negative pressure source (col. 3, liens 43-46), a pad (11) capable of placement within a wound, a drape (shell 11) capable of sealing and enclosing the pad on the wound. Svedman additionally discloses temperature sensors connected to a temperature regulator for controlling the temperature of the fluid.

In view Svedman, it would have been obvious to one having ordinary skill in the art to modify Fleischmann to include temperature sensors connected to a temperature regulator in order to control the temperature of the fluid and thereby maintain the correct environment around the wound.

As regards claim 9, both Fleischmann and Svedman fail to teach that the fluid is circulated about in a flexible envelope having an inlet and an outlet. Instead, both Fleischmann and Svedman disclose alternate means for circulating fluid therein.

Absent a critical teaching and/or a showing of unexpected results derived from circulating fluid in a flexible envelope, the examiner contends that the means in which the fluid is circulated is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claim 10, the tubing (16) which allow the supply and removal of the fluid in the region is partially sealed with the drape between the pad and drape.

As regards claims 12 and 18, Fleischmann discloses a process and device for application of active substances to a wound surface area, which anticipates applicant's presently claimed invention. More specifically, Fleischmann discloses a negative pressure source, a pad (12) for placement within a wound of a mammel (Fig. 1), a

Art Unit: 3743

cover/drape (14) capable of maintaining a reduced pressure within the wound; a fluid communication means (16) for communication between the negative pressure source and the pad.

Fleischmann fails to teach a cooling element for actively cooling the pad or a heating element. However, Svedman discloses a pad having a cover, a negative pressure source, fluid communication means and temperature sensors connected to a temperature regulator for controlling the temperature of the fluid thereby heating or cooling the wound (col. 6, lines 8-15). Therefore, a heating element or cooling element must necessarily be present in the device of Svedman.

In view of Svedman, it would have been obvious to one having ordinary skill in the art to provide Fleischmann with temperature sensors, a heating and/or cooling element connected to a temperature regulator for controlling the temperature of the fluid so as to heat or cool the wound (6, lines 8-15).

As regards claim 19, the pad is capable of being heated subsequent to being cooled.

Response to Arguments

9. Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

10. Claims 14-17 and 25-27 are allowed.

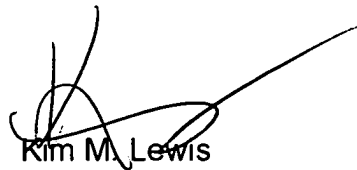
Art Unit: 3743

11. Claims 20, 21, 22, 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571)272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
January 24, 2005